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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/854,311

05/10/2001

Joseph Neev

NEEVJ-11087.PAT

7823

56549

7590

08/07/2009

Law Office of Richard B. Cates  
2629 Manhattan Avenue  
PMB-273  
Hermosa Beach, CA 90254

EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

08/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/854,311	<b>Applicant(s)</b> NEEV, JOSEPH	
	<b>Examiner</b> david shay	<b>Art Unit</b> 3769	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on February 11, 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-23, 25, 29, 30, 33-35, 38, 45-51, 54, 55 and 57-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23, 25, 29, 30, 33-35, 38, 45-51, 54, 55 and 57-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on October 1<sup>st</sup>, 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 3769

The substitute specification filed October 1, 2008 has not been entered, as it is not in conformance with § 1.125(c). Applicant has not provided a marked up copy of the specification to indicate the changes thereto.

The drawings are objected to because the figures have none of the elements labeled with indicia indicative of their function. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “generally solid absorbing material”, which is part of the device and the “device sized and configured to be held in the hand” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

Art Unit: 3769

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendments filed February 11, 2009; October 1, 2008; January 11, 2008; and April 24, 2007 are objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “a system for enhancing or improving the transcutaneous or transdermal delivery of various topical substances, chemicals, or drugs”; “to prevent any emitted energy from reaching the target area of the skin without being absorbed by the intermediate substance”; and “without removing skin tissue from the target area”.

Applicant is required to cancel the new matter in the reply to this Office Action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-23, 25, 29, 33-35, 38-40, 45-51, 54, 55, and 57-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on “device sized and configured to be held in the hand”; “thereby to enhance transdermal drug delivery”; “to prevent any emitted energy from reaching the target area of the skin without being absorbed by the intermediate substance”; and “without removing skin tissue from the target area”.

Art Unit: 3769

Claims 21-23, 25, 29, 33-35, 38-40, 45-51, 54, 55, and 57-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claims the exact meaning of the terms “to prevent any emitted energy from reaching the target area of the skin without being absorbed by the intermediate substance” and “without removing skin tissue from the target area” is unclear and the term lacks positive antecedent basis in the specification as originally filed.

Claims are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Neev (WO '438).

See Figures 11A, 11B, 13A-E, and the disclosure associated therewith wherein the absorbing material is considered “generally solid” since it forms a film which remains on the skin throughout wax depillation.

Claims 21-23, 25, 29, 33-35, 38-40, 45-51, 54, and 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neev (WO '438) in combination with Eppstein et al (6,530,915). Neev (WO '438) teaches a device as claimed, including a radiation source in combination with a highly absorbing substance not contacting the tissue, to treat e.g. acne, see Figures 11A, 11B, 13A-E, 18, 19, and the disclosure associated therewith wherein the absorbing material is not specifically mentioned as solid and does not teach the particular intermediate substance. Eppstein et al (6,530,915) teach a photothermal structure wherein an absorbing substance is suspended in a carrier that is then printed onto a substrate which can include agar or paper. It would have been obvious to the artisan of ordinary skill to employ the photothermal structure and method of Eppstein et al (6,530,915) in the device and method of Neev (WO '438),

Art Unit: 3769

since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and the various intermediate materials such as agar and tracing paper are equivalent to the liquids of Neev (WO '438), as shown by Eppstein et al (6,530,915), or, alternatively, to use the separate thermally conductive and radiation absorptive materials and methods of Neev (WO '438) in the device and method of Eppstein et al (6,530,915), since this would enable the treatment and device to be customized to the patient more easily and quickly, and to manipulate the proportion of absorbent material in the mixture so as to cause a certain percentage of the laser light to be converted into heat since this is not critical; is well within the scope of one having ordinary skill in the art; and provides no unexpected result, and to provide the 8 mm<sup>2</sup> and greater spot sizes, since this will allow larger areas to be treated more quickly, thus producing a device and method such as claimed.

Claims 55-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neev (WO '438) in combination with Eppstein et al (6,530,915), as applied to claims 21-23, 25, 29, 33-35, 38-40, 45-51, 54, and 65-69, and further in combination with Eckhouse et al. Eckhouse et al teach the desirability of applying substances to the applicator portion of the device. It would have been obvious to the artisan of ordinary skill to include the substance as part of the device, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result, and can provide cooling, as taught by Eckhouse et al, to configure the device to be cylindrical, since this is not critical; is well within the skill of one having ordinary skill in the art; would make the device more easily graspable and manipulable by the hand; and provides no unexpected result; to include the substance in the form of a cap, since these are typically used in contact medical devices for sterility purposes, official notice of which

Art Unit: 3769

is hereby taken, and to use an energy source which outputs less than 5 watts, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result, thus producing a device such as claimed.

Applicant's arguments with respect to claims 21-23, 25, 29, 33-35, 38-40, 45-51, 54, 55, and 57-69 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30

Art Unit: 3769

p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769